REMARKS

In the Office Action dated July 5, 2001, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following seven separate and distinct inventions:

I. Claims 1-18 and 36, drawn to a purified preparation of human undifferentiated embryonic stem cells, and a method of isolating and a method of testing fibroblast cell strains as a feeder layer to promote embryonic stem cell growth and limit differentiation, classified in class 435, subclass 347; class 435, subclass 363; and class 435, subclass 363.

II. Claims 19-28, drawn to a method of inducing unidirectional somatic cell differentiation, a method of isolating the committed progenitor cell from a population of differentiated cells, and an isolated differentiated cell, classified in class 435, subclass 327; and classified in class 435, subclass 327.

III. Claim 29, drawn to the cell line HES-1, classified in class 424, subclass 93.27.

IV. Claim 30, drawn to the cell line HES-2, classified in class 424, subclass 93.27.

V. Claims 31 and 32, drawn to a fibroblast cell strain suitable for the promotion of embryonic stem cell growth derived from mouse strains 129/Sv, CBA or 129/SvxC57/B16, classified in class 424, subclass 93.27.

VI. Claims 33 and 34, drawn to a method of preserving a differentiated or undifferentiated cell wherein the cell undergoes vitrification, classified in class 435, subclass 325.

VII. Claim 35, drawn to a method of preventing and treating a congenital disease comprising genetically modifying an undifferentiated stem cell and inducing differentiation to a somatic cell line for transplantation, classified in class 800, subclass 3.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group II, claims 19-28, drawn to a method of inducing unidirectional somatic cell differentiation, a method of isolating the committed progenitor cell from a population of differentiated cells, and an isolated differentiated cell. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, the Examiner asserts that Groups I and III-V are unrelated, as the Examiner contends that the embryonic cell of Group I, the two clonally-derived cell lines of Groups III and IV, and the fibroblast of Group V are materially different cells.

The Examiner further contends that the cells of Groups III-V are related to the methods of Groups I, II and IV as product and process of use. The Examiner states that these groups represent distinct inventions since the cells of Groups III-V can be used in processes different from the processes of Groups I, II and IV.

Furthermore, the Examiner asserts that the embryonic cell of Group I and the method of treating a congenital disease of Group VII, which are related to each other as product and process of use, represent distinct inventions. The Examiner contends that a congenital disease can be treated by more conventional means, such as with a drug or diet (other than using the undifferentiated embryonic cell of Group I).

Moreover, the Examiner asserts that Groups I, II, and VI are unrelated, as the Examiner contends that each group represents a different method which requires different steps and materials, and results in different effects.

In response, Applicants respectfully submit that Groups I-VII are merely different aspects of a single invention. More specifically, Applicants submit that Group I is drawn to human undifferentiated embryonic stem cells, and a method of preparing such embryonic stem cells which involves the use of fibroblast cells as a feeder layer. Groups III and IV are directed to specific undifferentiated cell lines prepared using the method of Group I. Group V is directed to a fibroblast cell which is suitable for use in the methods of Group I for the preparation of undifferentiated embryonic stem cells. Group VI is simply directed to a process for preserving the embryonic stem cells of Group I. Groups II and VII are directed to aspects of the invention as to how to use the embryonic stem cells of Group I in producing a differentiated cell and in treating a congenital disease. Clearly, Groups I-VII are closely related to one another, and are not "independent and distinct".

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts.

Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined seven groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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